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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,161	12/10/2003	Jutaro Shudo	TEIK-001CON	5937

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EXAMINER

GEORGE, KONATA M

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/733,161

Applicant(s)

SHUDO ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13,14 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 1-8 and 13-22 are pending in this application.

#### ***Information Disclosure Statement***

1. The information disclosure statements (IDS) submitted on February 17, 2004, March 3, 2004 and April 22, 2004 are noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Priority***

2. Please be advised that US Patent Application No. 09/813,652 has issued to Patent No. 6,698,162 and should be reflected in the priority statement at the beginning of the specification.

#### ***Restriction Requirement***

3. Applicant's election with traverse of claims 13-18 in the reply filed on June 30, 2004 is acknowledged, however, applicants did not provide any arguments against the restriction. Therefore, the requirement is deemed proper and is therefore made FINAL.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13, 14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caplan (US 2003/0035810 A1) in view of Gueret (US 6,623,751 B2) and Fischer et al. (US 6,455,066 B1).

Caplan discloses administering to subjects microorganisms. Paragraph [0047] discloses that the microorganisms administered to subjects are killed prior to administering to subject. Paragraph [0047] teaches that the microorganisms are killed via various methods such as heat, antibiotics, radioactivity (i.e. irradiation), etc. Paragraphs [0094] and [0097] teach that transdermal patches can be used in delivering the pharmaceutical composition. It is also taught the rate of delivery in the patches can be controlled by being dispersed in a polymer matrix or gel. The prior art does not teach the patch comprising a fibrous material and an adhesive gel composition, an anesthetic and the patch is sealed and comprises an aluminum layer. It is not taught that the topical patch is sterilized.

Gueret discloses a cosmetic, pharmaceutical or dermatological patch. The patch of the prior art includes one or more layers, comprising a hydrophilic gelling system and wherein the patch can contain a reinforcing member (col. 2, lines 19-26 and 35-37). The reinforcing member is made of woven or non-woven fabrics. The gelling system of the prior art contains a hydrocolloid associated with the gellan gum can be cellulose and derivatives, plant extrudates, water-soluble gelling polymers, etc. (col. 3, lines 23-61). Column 4, line 60 through column 5, line 39 teach that the composition also contains

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water, glycols, and an active agent. Column 6, lines 35-42 teach that packaging material can contain a removable cover formed from a metallic material (i.e. aluminum).

While Caplan discloses using microorganisms in transdermal patch it does not teach the structure of the patch, Gueret overcomes the deficiency by teaching a basic transdermal patch structure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the inventions was made to use the combine teachings of Gueret with Caplan to disclose the claimed invention. With respect to the topical patch preparation being sterilized, it is the position of the examiner that all transdermal patches must be sterile in order to prevent the transport of unwanted or toxic materials.

#### ***Allowable Subject Matter***

5. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach combining a nonviable microorganism with a local anesthetic in a topical patch preparation.

#### ***Conclusion***

6. Claims 13, 14 and 16-18 are rejected.

#### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is


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(571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600